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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,658	09/17/2003	Friedrich W. Kuehne	25708-0038	7719

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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/049,658		KUEHNE, FRIEDRICH W.	
	Examiner		Art Unit	
	Vickie Kim		1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-28 is/are pending in the application.
- 4a) Of the above claim(s) 10-13, 15-17, 21-24 and 26-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-9, 14, 18-20 and 25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

RCE acknowledged

A request for continued examination(RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/1/06 has been entered.

Status of application

Claims 8-9, 14, 18-20 and 25 read on the elected species(i.e. pancreatic carcinoma) and presented for examination. All remaining claims not drawn to the elected invention are withdrawn from further consideration as being non-elected.

Response to Arguments

1. Claim Objection is withdrawn in view of the amendment filed 12/1/06.
2. Applicant's arguments with respect to claims 8-9, 14, 18-20 and 25 have been considered but are not persuasive.

Applicant argued that the examiner must propose some modification of a particular reference or a combination thereof with another reference in order to arrive at the claimed invention(see remarks at page 7, 4th paragraph).

This examiner clearly states that the motivation of modification of a secondary reference to remedy the deficiency found in primary reference, in this case, primary

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reference(CA'714,Kuehne et al) teaches cancer treatment(e.g. adenocarcinoma) using an aqueous solution containing a stabilized chlorite solution. Although primary reference does not explicitly disclose the specific species of the cancer benefited by the administration of chlorite solution. As reemphasized by applicant's remarks(i.e. unpredictability of drug treatment in cancer treatment), the cancer treatment has to be individualized based on types of cancer, and that is the reason that this examiner combined to remedy the deficiency of primary reference where primary reference does not entail the specific types of adenocarcinoma in his patent. Secondary reference(Kern et al US'097) teaches about adenocarcinoma which is characterized by a reduced expression of the DCC, and the adenocarcinoma(subgeneric name) includes pancreatic cancer which has same characteristics(reduced DCC expression) . Because of unpredictability recognized in cancer treatment, one would have motivated to find the specific types that is classified adenocarcinoma and extend Kuehne's chlorite treatment into pancreatic carcinoma with reasonable expectation of success. One of ordinary skill in the art to make this modification because the assurance and reliance for the drug treatment(given) is critical factor to increase successful rate and patient compliance.

Thus, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Again, the examiner's conclusion of obviousness is based upon the references cited which are argued by applicant as nonanalogous to each other to

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combine, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

The claimed invention is obvious when these references are taken together(CA'714 in view of US'097), and the rejection is maintained as set forth in previous office action.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 8-9, 14, 18-20 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuehne et al(CA1268714, 1990) in view of Kern et al(US 5712097).

The claims are drawn to a method of treating cancer which is characterized by a reduced expression of the DCC protein, comprising administering an aqueous solution comprising a stabilized chlorite solution.

Kuehne et al(CA'714, hereinafter) teaches a stabilized chlorite solution and its use in cancer treatment(e.g. metastatic solid tumors such as primary or metastatic adenocarcinoma, see abstract and page 1, last paragraph of English translated version)

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The claims differ in that because they require pancreatic carcinoma.

Kern et al(US'097) teaches that a primary pancreatic carcinoma is adenocarcinoma that is associated with DCC, see example 1 at col. 17.

Thus, it would have been obvious to one of ordinary skill in the art at that time of the invention was made to substitute adenocarcinoma with pancreatic carcinoma. The recitation "the carcinoma characterized by reduced DCC expression" is inherently possessed and regardless knowing this activity or not, the treatment of pancreatic cancer would be achieved when chlorite solution is administered.

One would have been motivated to make such substitution, with reasonable expectation of success, because the effectiveness of chlorite solution against pancreatic cancer is well proven by CA'714, and it is always desired to extend the medical utility by substituting the effective therapeutic modality. Since the effectiveness is well proven and clearly suggested by CA'714, such substitution to include pancreatic carcinoma would increase industrial applicability and maximize the benefits of drug treatment against cancer therapy.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

1. No claim is allowed.

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2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579.

The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
December 22, 2006
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